

US008167943B2

(12) **United States Patent**  
**Carter et al.**

(10) **Patent No.:** **US 8,167,943 B2**  
(45) **Date of Patent:** **May 1, 2012**

(54) **MATERIALS AND METHODS FOR IMPROVED BONE TENDON BONE TRANSPLANTATION**

(75) Inventors: **Kevin C. Carter**, Gainesville, FL (US); **Michael Esch**, Alachua, FL (US); **Paul LaRochelle**, Satellite Beach, FL (US); **Jim Gross**, Alachua, FL (US)

(73) Assignee: **RTI Biologics, Inc.**, Alachua, FL (US)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 279 days.

(21) Appl. No.: **10/846,399**

(22) Filed: **May 14, 2004**

(65) **Prior Publication Data**

US 2004/0210308 A1 Oct. 21, 2004

**Related U.S. Application Data**

(63) Continuation of application No. 09/528,034, filed on Mar. 17, 2000, now Pat. No. 6,805,713, which is a continuation-in-part of application No. 09/481,319, filed on Jan. 11, 2000, now Pat. No. 6,497,726.

(51) **Int. Cl.**  
**A61F 2/08** (2006.01)

(52) **U.S. Cl.** ..... **623/13.17**

(58) **Field of Classification Search** ..... 623/13.11-13.2, 623/11.11, 16.11, 18.11; 606/53, 54, 60, 606/246-249, 62-65, 300, 321, 88  
See application file for complete search history.

(56) **References Cited**

**U.S. PATENT DOCUMENTS**

4,400,833 A 8/1983 Kurland  
4,605,414 A 8/1986 Czajka  
4,804,383 A \* 2/1989 Rey et al. .... 623/13.11

4,927,421 A 5/1990 Goble et al.  
4,942,875 A \* 7/1990 Hlavacek et al. .... 606/230  
5,004,474 A \* 4/1991 Fronk et al. .... 623/13.14  
5,062,843 A 11/1991 Mahony, III  
5,067,962 A \* 11/1991 Campbell et al. .... 128/898  
5,078,744 A \* 1/1992 Chvapil ..... 606/86 R  
5,092,887 A 3/1992 Gendler  
5,139,520 A \* 8/1992 Rosenberg ..... 606/87  
5,211,647 A 5/1993 Schmieding  
5,217,495 A \* 6/1993 Kaplan et al. .... 623/13.18

(Continued)

**FOREIGN PATENT DOCUMENTS**

FR 2739773 4/1997

(Continued)

**OTHER PUBLICATIONS**

Lambert, Vascularized patellar tendon graft with rigid internal fixation for anterior cruciate ligament insufficiency, *Clinical Orthopaedics and Related Research*, 1983; 172: 85-89.

(Continued)

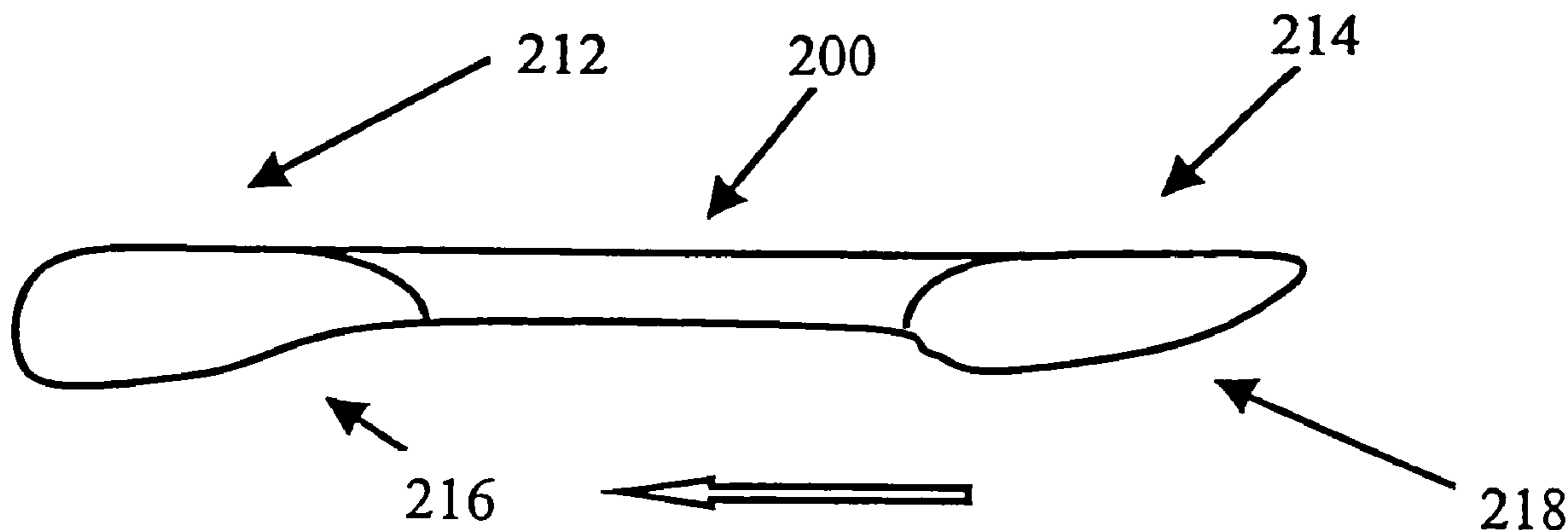
*Primary Examiner* — Alvin J Stewart

(74) *Attorney, Agent, or Firm* — McAndrews, Held & Malloy Ltd.

(57) **ABSTRACT**

Disclosed herein is an improved Bone Tendon Bone graft for use in orthopedic surgical procedures. Specifically exemplified herein is a Bone Tendon Bone graft comprising one or more bone blocks having a groove cut into the surface thereof, wherein said groove is sufficient to accommodate a fixation screw. Also disclosed is a method of harvesting grafts that has improved efficiency and increases the quantity of extracted tissue and minimizes time required by surgeon for implantation.

**18 Claims, 7 Drawing Sheets**





U.S. PATENT DOCUMENTS

5,234,430	A	8/1993	Huebner	
5,263,984	A *	11/1993	Li et al.	623/13.18
5,282,802	A	2/1994	Mahony, III	
5,320,115	A *	6/1994	Kenna	128/898
5,366,457	A *	11/1994	McGuire et al.	606/86 R
5,370,662	A	12/1994	Stone et al.	
5,383,878	A	1/1995	Roger et al.	
5,391,169	A	2/1995	McGuire	
5,393,302	A	2/1995	Clark et al.	
RE34,871	E	3/1995	McGuire et al.	
5,397,356	A	3/1995	Goble et al.	
5,397,357	A	3/1995	Schmieding et al.	
5,425,733	A	6/1995	Schmieding	
5,425,767	A	6/1995	Steininger et al.	
5,437,675	A	8/1995	Wilson	
5,443,509	A	8/1995	Boucher et al.	
5,454,811	A	10/1995	Huebner	
5,496,326	A	3/1996	Johnson	
5,507,813	A	4/1996	Dowd et al.	
5,562,669	A *	10/1996	McGuire	623/13.12
5,562,671	A	10/1996	Goble et al.	
5,571,184	A	11/1996	DeSatnick	
5,632,748	A	5/1997	Beck, Jr. et al.	
5,681,314	A	10/1997	Derouin et al.	
5,688,285	A	11/1997	Yamada	
5,733,289	A	3/1998	Seedhom et al.	
5,766,250	A	6/1998	Chervitz et al.	
5,772,664	A	6/1998	DeSatnick et al.	
5,871,504	A	2/1999	Eaton et al.	
5,897,570	A	4/1999	Palleva et al.	
5,951,560	A	9/1999	Simon et al.	
5,961,520	A	10/1999	Beck, Jr. et al.	
5,984,966	A	11/1999	Kiema et al.	
6,001,100	A	12/1999	Sherman et al.	
6,099,530	A	8/2000	Simonian et al.	
6,099,568	A *	8/2000	Simonian et al.	623/13.11
6,190,411	B1	2/2001	Lo	
6,200,347	B1	3/2001	Anderson et al.	
6,210,440	B1	4/2001	Stone et al.	
6,235,057	B1	5/2001	Roger et al.	
6,283,973	B1	9/2001	Hubbard et al.	
6,306,168	B1	10/2001	Berrang et al.	
6,355,066	B1	3/2002	Kim	
6,379,361	B1 *	4/2002	Beck et al.	606/72
6,440,134	B1	8/2002	Zaccherotti et al.	
6,461,373	B2	10/2002	Wyman et al.	
6,533,816	B2	3/2003	Sklar	
6,780,187	B2	8/2004	Supinski	
6,893,462	B2	5/2005	Buskirk et al.	
7,309,356	B2 *	12/2007	Steiner	623/13.14
7,347,872	B2 *	3/2008	Goulet et al.	623/13.17
7,357,947	B2 *	4/2008	Nimni	424/484
7,513,910	B2 *	4/2009	Buskirk et al.	623/13.17
7,648,676	B2 *	1/2010	Mills et al.	422/28
7,727,278	B2 *	6/2010	Olsen et al.	623/13.12
7,776,089	B2 *	8/2010	Bianchi et al.	623/13.12
D625,822	S *	10/2010	Lewis et al.	D24/155
D630,329	S *	1/2011	Goede et al.	D24/155
2002/0165611	A1	11/2002	Enzerink et al.	

FOREIGN PATENT DOCUMENTS

JP	A H05-502395	4/1993
JP	A H09-10245	1/1997
JP	A H10-155829	6/1998
JP	10155820	8/1998
WO	WO9822047	5/1998
WO	WO 9921515	5/1999

OTHER PUBLICATIONS

Blevins et al., The effects of donor age and strain rate on the biomechanical properties of bone-patellar tendon-bone allografts. American Journal of Sports Medicine, 1994; 22(3): 328-333.  
 Noyes et al., Bone-patellar ligament-bone and fascia lata allografts for reconstruction of the anterior cruciate ligament. Journal of Bone and Joint Surgery, 1990; 72A(8); 1125-1136.

Fahey et al., Bone tunnel enlargement after anterior cruciate ligament replacement, American Journal of Sports Medicine, 1994; 22(3): 410-414.  
 Indelicato et al., The results of fresh-frozen patellar tendon allografts for chronic anterior cruciate ligament deficiency of the knee, American Journal of Sports Medicine, 1992; 20(2): 118-121.  
 Indelicato et al., Clinical comparison of freeze-dried and fresh frozen patellar tendon allografts for anterior cruciate ligament reconstruction of the knee, American Journal of Sports Medicine, 1990; 18(4): 335-342.  
 Liu et al., Biomechanics of two types of bone-tendon-bone grafts for ACL reconstruction, Journal of bone and joint surgery, 1995; 77B(2); 232-235.  
 Office Action dated Dec. 7, 2001 for U.S. Appl. No. 09/481,319, Inventor Kevin C. Carter, Conf. No. 5495.  
 Office Action dated Nov. 18, 2003 for U.S. Appl. No. 09/528,034, Inventor Kevin C. Carter, Conf. No. 4253.  
 Office Action dated Mar. 3, 2003 for U.S. Appl. No. 09/528,034, Inventor Kevin C. Carter, Conf. No. 4253.  
 Office Action dated Sep. 11, 2002 for U.S. Appl. No. 09/528,034, Inventor Kevin C. Carter, Conf. No. 4253.  
 Office Action dated Dec. 18, 2002 for U.S. Appl. No. 09/528,034, Inventor Kevin C. Carter, Conf. No. 4253.  
 Office Action dated Jan. 29, 2007 for U.S. Appl. No. 09/924,110, Inventor Kevin C. Carter, Conf. No. 9738.  
 Office Action dated May 2, 2006 for U.S. Appl. No. 09/924,110, Inventor Kevin C. Carter, Conf. No. 9738.  
 Office Action dated Oct. 18, 2005 for U.S. Appl. No. 09/924,110, Inventor Kevin C. Carter, Conf. No. 9738.  
 Office Action dated Apr. 18, 2005 for U.S. Appl. No. 09/924,110, Inventor Kevin C. Carter, Conf. No. 9738.  
 Office Action dated Sep. 28, 2004 for U.S. Appl. No. 09/924,110, Inventor Kevin C. Carter, Conf. No. 9738.  
 Office Action dated Sep. 24, 2003 for U.S. Appl. No. 09/924,110, Inventor Kevin C. Carter, Conf. No. 9738.  
 Office Action dated Apr. 17, 2009 for U.S. Appl. No. 11/796,282, Inventor Kevin C. Carter, Conf. No. 3857.  
 Office Action dated Dec. 3, 2008 for U.S. Appl. No. 10/013,328, Inventor Kevin C. Carter, Conf. No. 1297.  
 Office Action dated Apr. 2, 2008 for U.S. Appl. No. 10/013,328, Inventor Kevin C. Carter, Conf. No. 1297.  
 Office Action dated Aug. 8, 2007 for U.S. Appl. No. 10/013,328, Inventor Kevin C. Carter, Conf. No. 1297.  
 Office Action dated May 25, 2006 for U.S. Appl. No. 10/013,328, Inventor Kevin C. Carter, Conf. No. 1297.  
 Office Action dated Oct. 5, 2005 for U.S. Appl. No. 10/013,328, Inventor Kevin C. Carter, Conf. No. 1297.  
 Office Action dated Apr. 6, 2005 for U.S. Appl. No. 10/013,328, Inventor Kevin C. Carter, Conf. No. 1297.  
 Office Action dated Jan. 23, 2004 for U.S. Appl. No. 10/013,328, Inventor Kevin C. Carter, Conf. No. 1297.  
 Office Action dated May 10, 2011 for U.S. Appl. No. 12/563,830, Inventor Kevin C. Carter, Conf. No. 7176.  
 Office Action dated Mar. 18, 2011 for U.S. Appl. No. 11/796,282, Inventor Kevin C. Carter, Conf. No. 3857.  
 Office Action dated Aug. 5, 2010 for U.S. Appl. No. 11/796,282, Inventor Kevin C. Carter, Conf. No. 3857.  
 Office Action dated Dec. 7, 2009 for U.S. Appl. No. 11/796,282, Inventor Kevin C. Carter, Conf. No. 3857.  
 Japanese Patent Office, Notice of Reasons for Rejection, in Japanese Patent Application No. 2006-279110, dated May 28, 2010.  
 Japanese Patent Office, Notice of Reasons for Rejection, in Japanese Patent Application No. 2001-551423, dated Jun. 2, 2005.  
 Japanese Patent Office, Decision of Rejection, in Japanese Patent Application No. 2001-551423, dated Jun. 28, 2006.  
 Japanese Patent Office, Pre-Appeal Examination Report, in Japanese Patent Application No. 2001-551423, dated Feb. 27, 2007.  
 Japanese Patent Office, Questioning, in Japanese Patent Application No. 2001-551423, dated Jul. 11, 2008.  
 Japanese Patent Office, Appeal Decision, in Japanese Patent Application No. 2001-551423, dated Mar. 19, 2009.  
 Canadian Patent Office, Office Action, in Canadian Patent Application No. 2,397,071, dated Sep. 12, 2005.



- European Patent Office, Communication pursuant to Article 96(2) EPC, in European Patent Application No. 01 902 012.2-2310, dated Mar. 9, 2004.
- European Patent Office, Communication pursuant to Article 96(2) EPC, in European Patent Application No. 01 902 012.2-2310, dated Jul. 28, 2005.
- European Patent Office, Communication pursuant to Article 96(2) EPC, in European Patent Application No. 01 902 012.2-2310, dated May 5, 2006.
- European Patent Office, Summons to attend oral proceedings pursuant to Rule 71(1) EPC, in European Patent Application No. 01 902 012.2-2310, dated Nov. 22, 2007.
- European Patent Office, Communication under Rule 71(3) EPC, in European Patent Application No. 01 902 012.2-2310, dated Jun. 23, 2008.
- European Patent Office, Communication of a notice of opposition, in European Patent No. 1246585, dated Oct. 2, 2009.
- Gill Jennings & Every, Comments in response to notice of opposition, in European Patent No. 1246585, dated May 18, 2010.
- European Patent Office, Summons to attend oral proceedings pursuant to Rule 115(1) EPC, in European Patent No. 1246585, dated May 13, 2011.
- International Preliminary Examination Report for PCT/US01/01008 dated Apr. 15, 2003.
- International Search Report for PCT/US01/01008 dated Oct. 18, 2001.
- International Search Report for PCT/US02/24972 dated Apr. 21, 2003.
- International Search Report for PCT/US02/25018 dated Apr. 23, 2003.
- European Patent Office, Decision rejecting the opposition, in European Patent No. 1246585, dated Jan. 12, 2012.
- Canadian Intellectual Property Office, Response to Examiner's Report in Canadian Patent Application No. 2,397,071, dated Mar. 8, 2006.
- Japanese Patent Office, Response in Japanese Patent Application No. 2006-279110, dated Nov. 26, 2010.
- Japanese Patent Office, Response in Japanese Patent Application No. 2001-551423, dated Dec. 8, 2005.
- Japanese Patent Office, Response in Japanese Patent Application No. 2001-551423, dated Oct. 3, 2006.
- Japanese Patent Office, Response in Japanese Patent Application No. 2001-551423, dated Nov. 16, 2006.
- Japanese Patent Office, Response in Japanese Patent Application No. 2001-551423, dated Oct. 31, 2007.
- European Patent Office, Response in European Patent Application No. 01902012.2, dated Sep. 15, 2004.
- European Patent Office, Response in European Patent Application No. 01902012.2, dated Dec. 6, 2005.
- European Patent Office, Response in European Patent Application No. 01902012.2, dated Oct. 30, 2006.
- European Patent Office, Response in European Patent Application No. 01902012.2, dated May 8, 2007.
- European Patent Office, Response in European Patent Application No. 01902012.2, dated Jan. 25, 2008.
- European Patent Office, Response in European Patent Application No. 01902012.2, dated Feb. 19, 2008.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 09/481,319, dated May 7, 2002.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 09/481,319, dated Oct. 22, 2001.
- U.S. Patent and Trademark Office, Supplemental Amendment filed in U.S. Appl. No. 09/481,319, dated Jul. 31, 2002.
- U.S. Patent and Trademark Office, Amendment filed in U.S. Appl. No. 09/528,034, dated Mar. 10, 2004.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 09/528,034, dated Feb. 2, 2004.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 09/528,034, dated May 20, 2002.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 09/528,034, dated Sep. 2, 2003.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 09/528,034, dated Oct. 22, 2001.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 09/528,034, dated Nov. 11, 2002.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 09/924,110, dated Apr. 7, 2006.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 09/924,110, dated Feb. 11, 2004.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 09/924,110, dated Mar. 28, 2005.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 09/924,110, dated Jul. 11, 2003.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 09/924,110, dated Aug. 15, 2005.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 09/924,110, dated Nov. 2, 2006.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 09/924,110, dated Nov. 23, 2004.
- U.S. Patent and Trademark Office, Election Response filed in U.S. Appl. No. 10/013,328, dated Jul. 11, 2003.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 10/013,328, dated Feb. 8, 2008.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 10/013,328, dated Mar. 9, 2006.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 10/013,328, dated Mar. 19, 2007.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 10/013,328, dated May 4, 2009.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 10/013,328, dated Jul. 10, 2007.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 10/013,328, dated Jul. 14, 2004.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 10/013,328, dated Aug. 15, 2005.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 10/013,328, dated Oct. 2, 2008.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 10/013,328, dated Dec. 13, 2004.
- U.S. Patent and Trademark Office, Supplemental Election Response filed in U.S. Appl. No. 10/013,328, dated Nov. 10, 2003.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 11/796,282, dated Jan. 5, 2011.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 11/796,282, dated Apr. 7, 2010.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 11/796,282, dated Jul. 14, 2011.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 11/796,282, dated Aug. 17, 2009.
- U.S. Patent and Trademark Office, Supplemental Response filed in U.S. Appl. No. 11/796,282, dated Aug. 25, 2011.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 12/563,830, dated Jan. 3, 2011.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 12/563,830, dated Mar. 4, 2011.
- U.S. Patent and Trademark Office, Response filed in U.S. Appl. No. 12/563,830, dated Aug. 10, 2011.
- Japanese Patent Office, Notice of Reason for Rejection, in Japanese patent application No. 2006-279110, dated Apr. 4, 2011.

\* cited by examiner

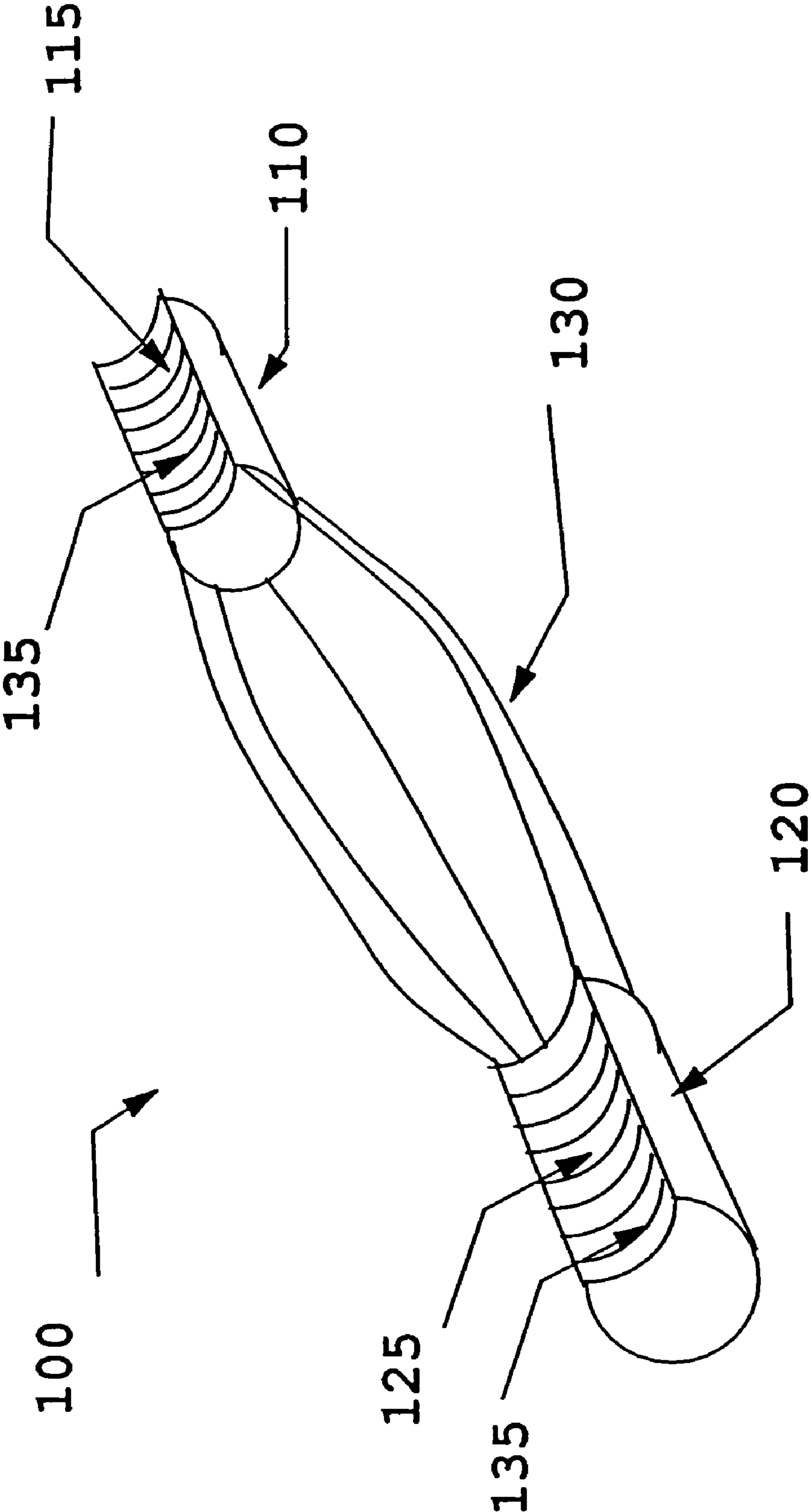


FIGURE 1

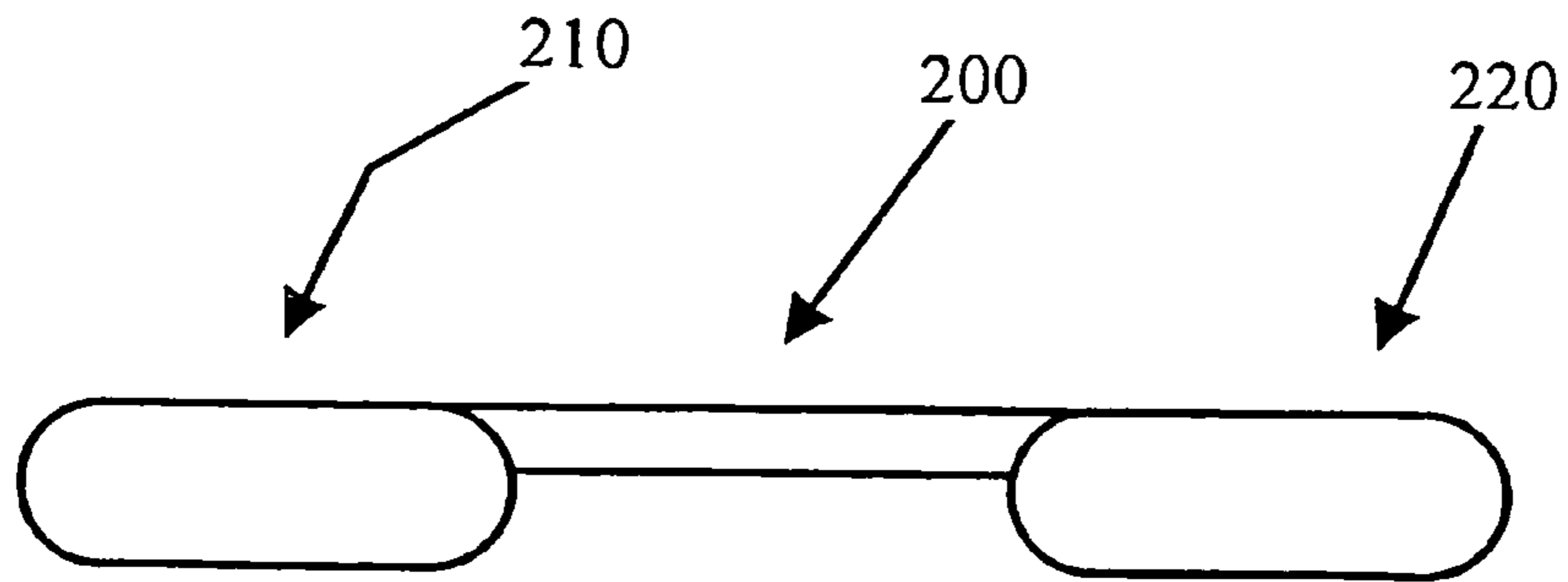


Figure 2A

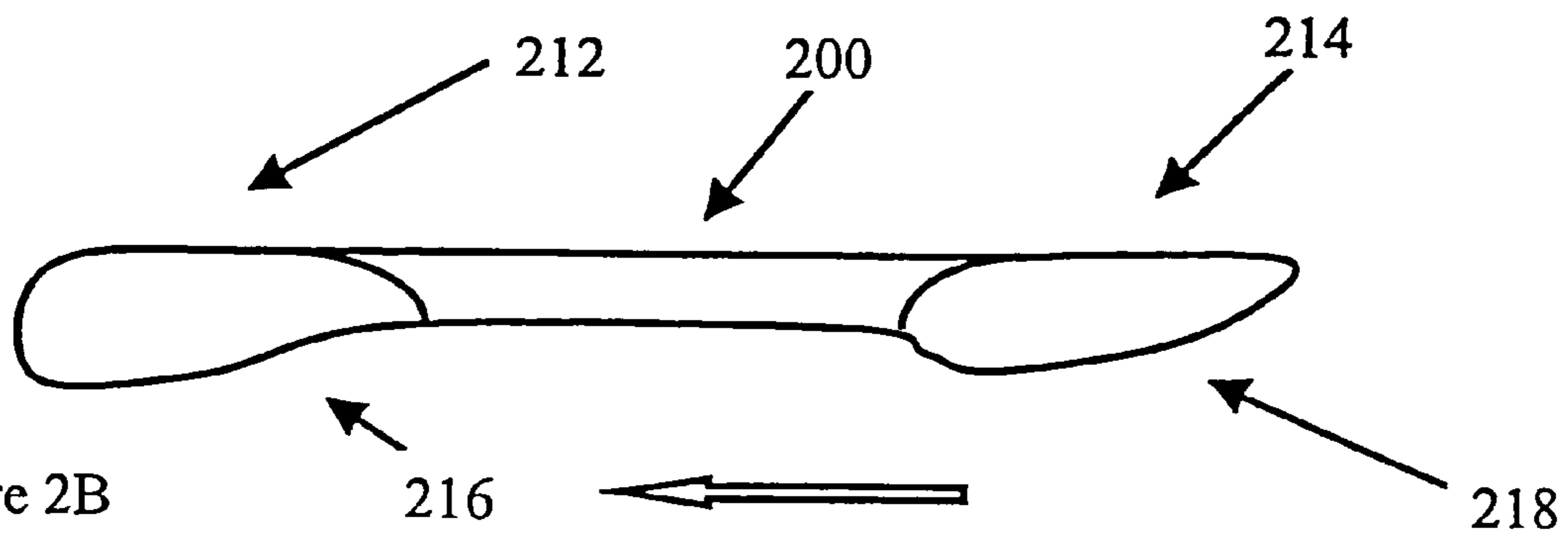


Figure 2B

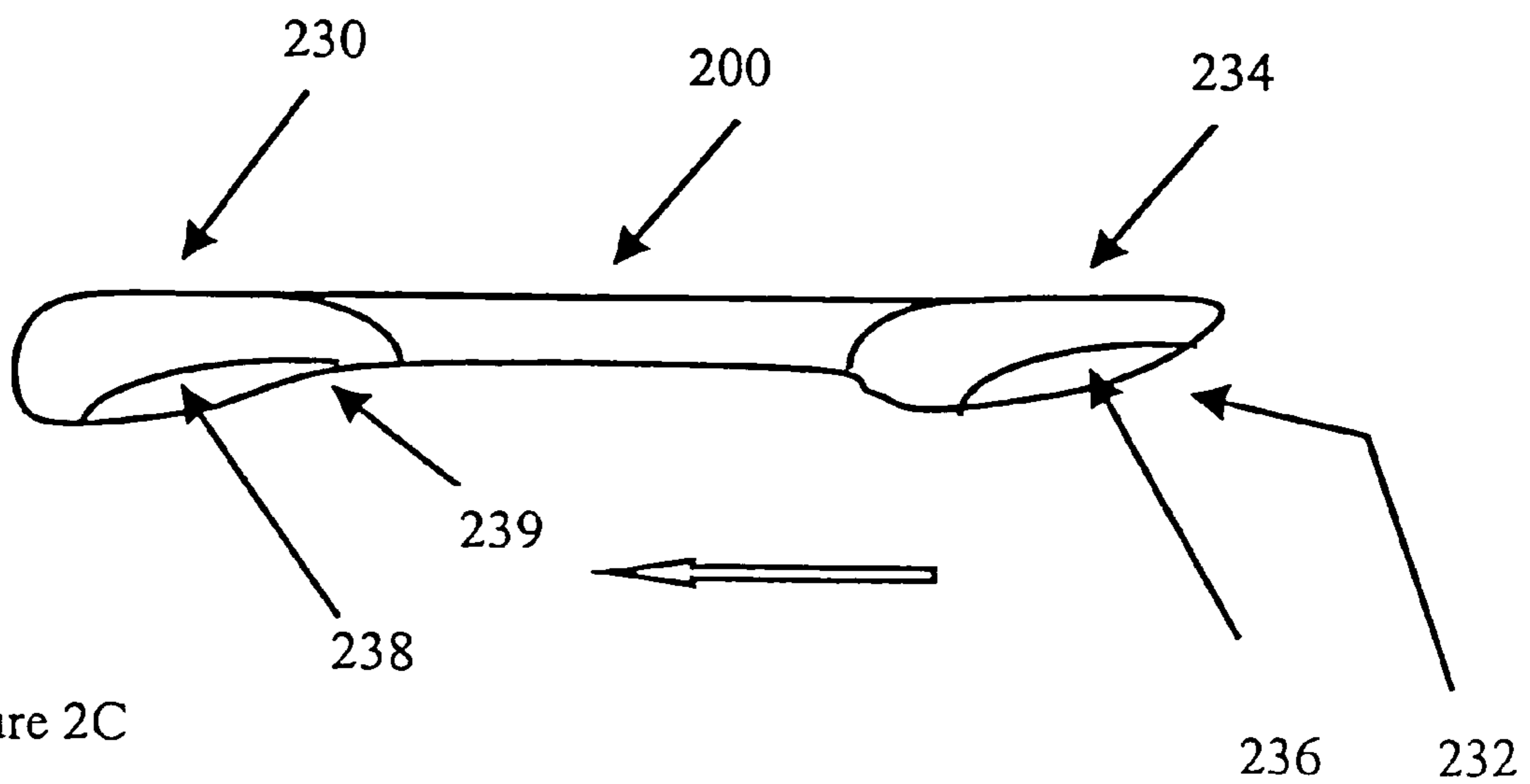


Figure 2C

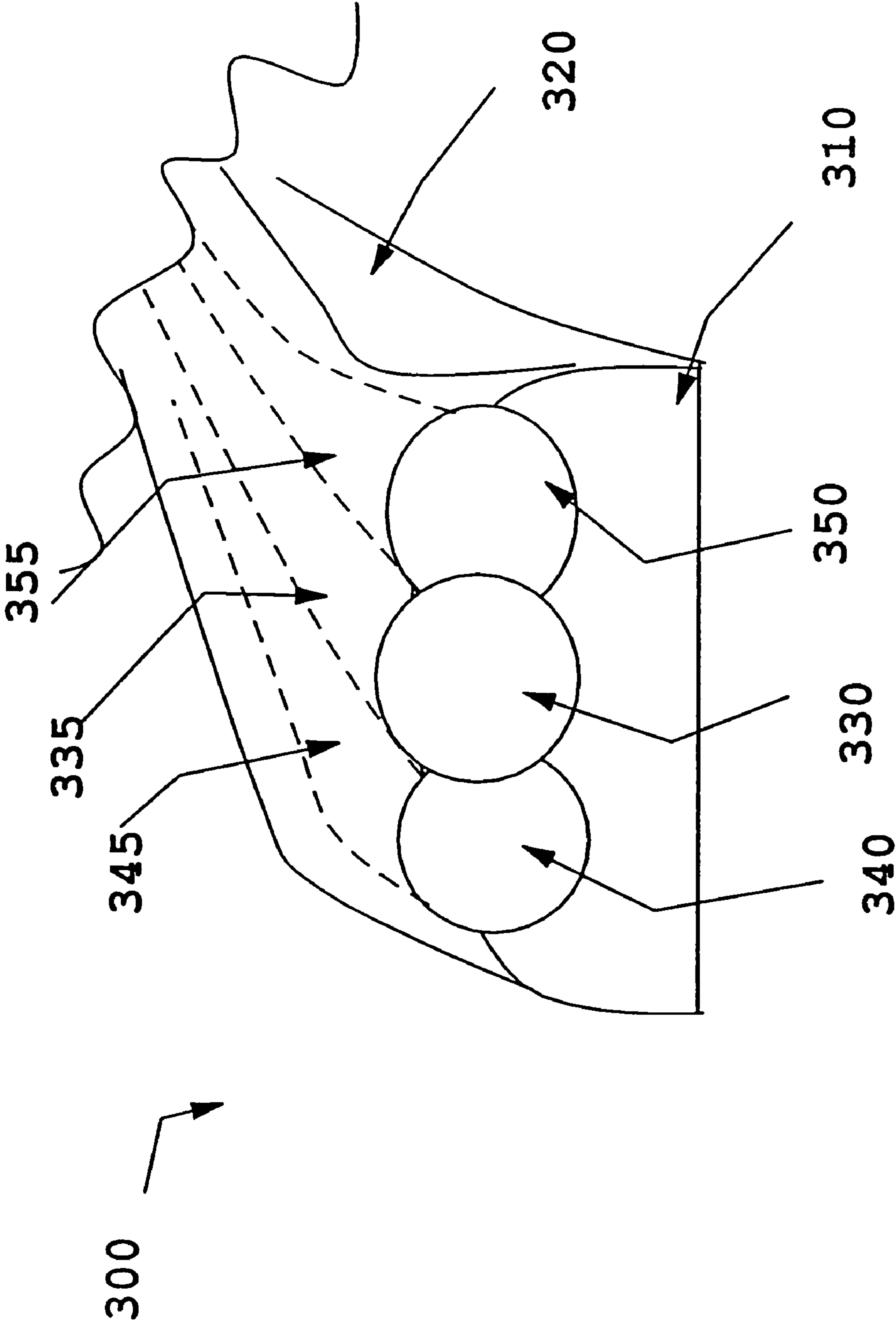


FIGURE 3



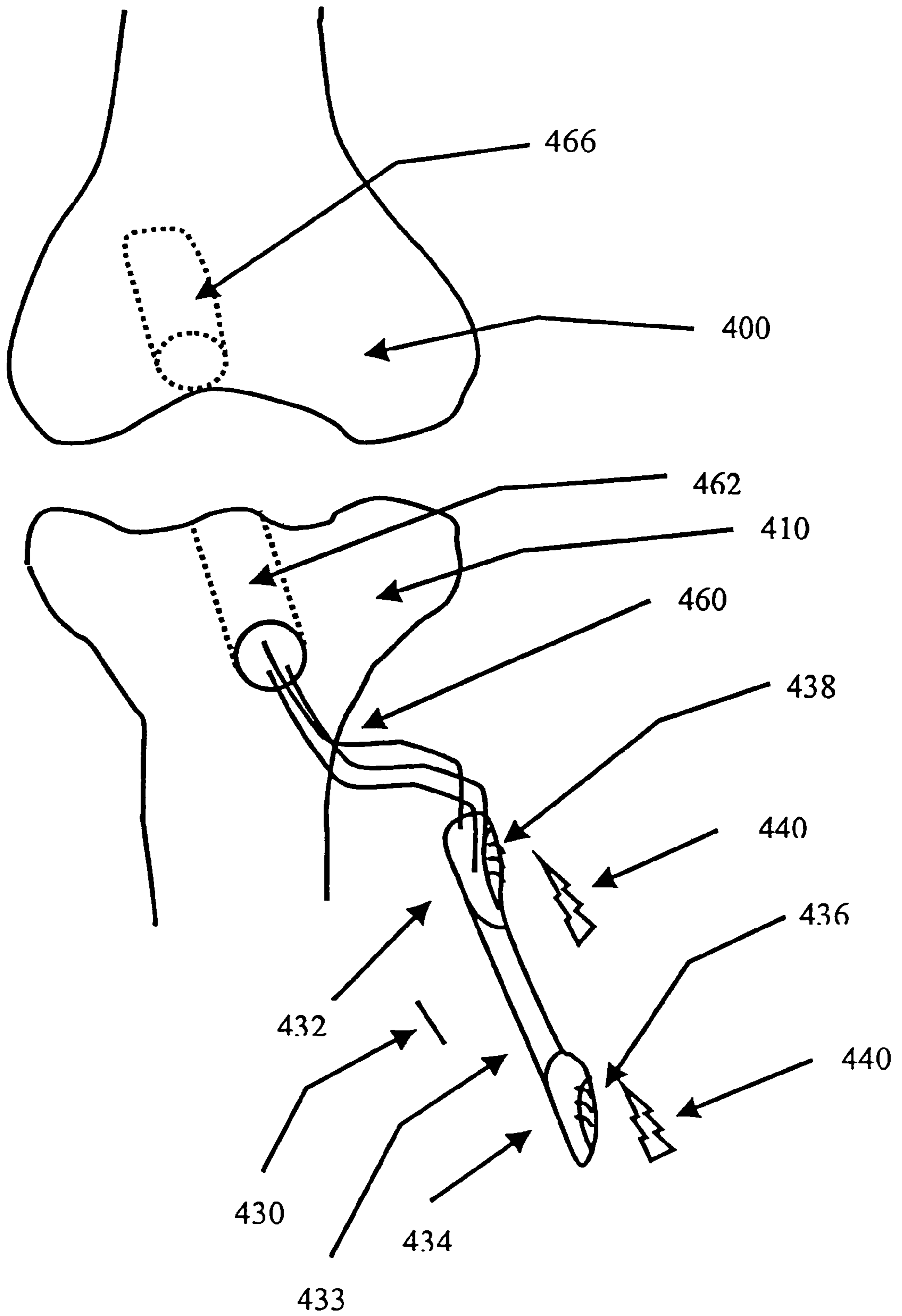


Figure 4

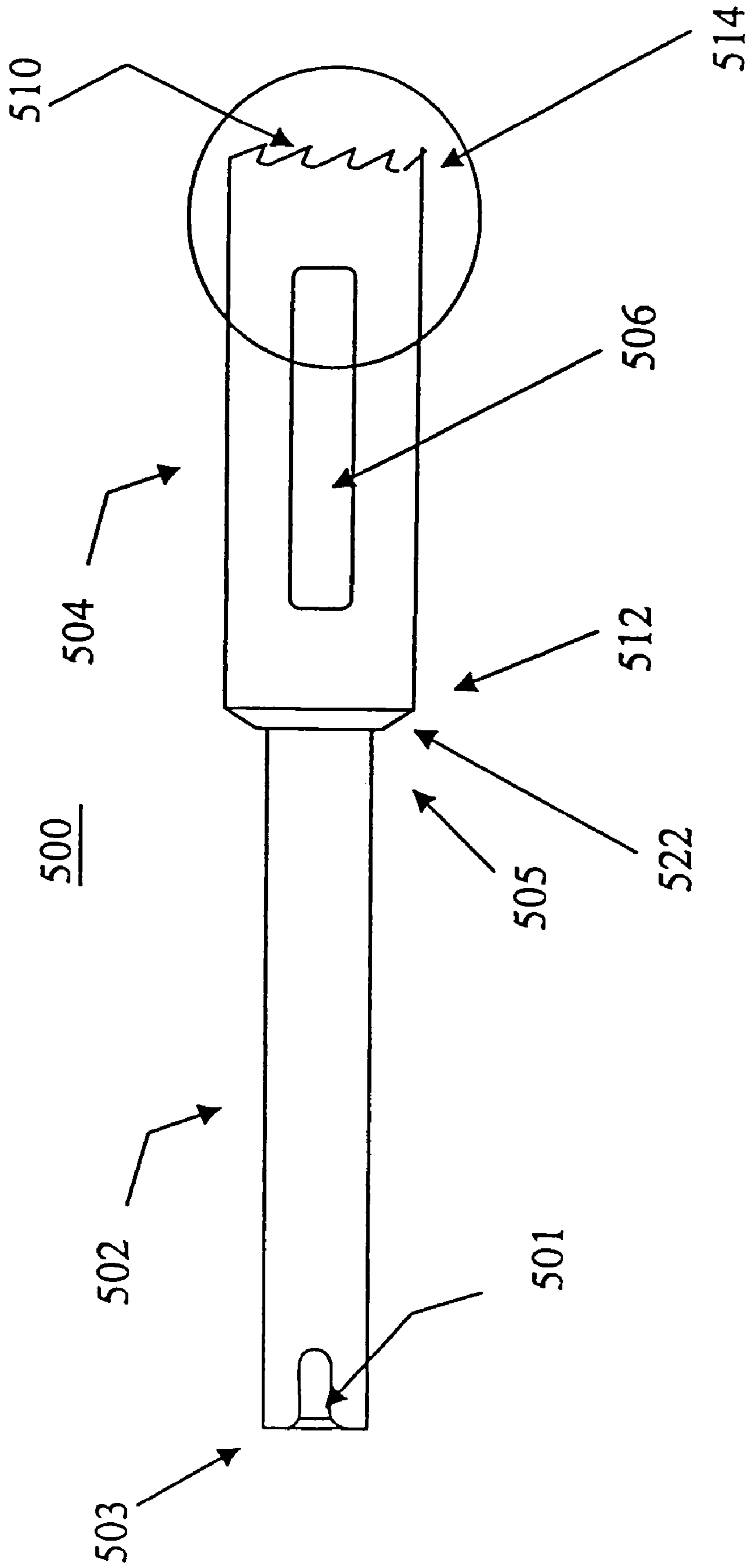


Figure 5



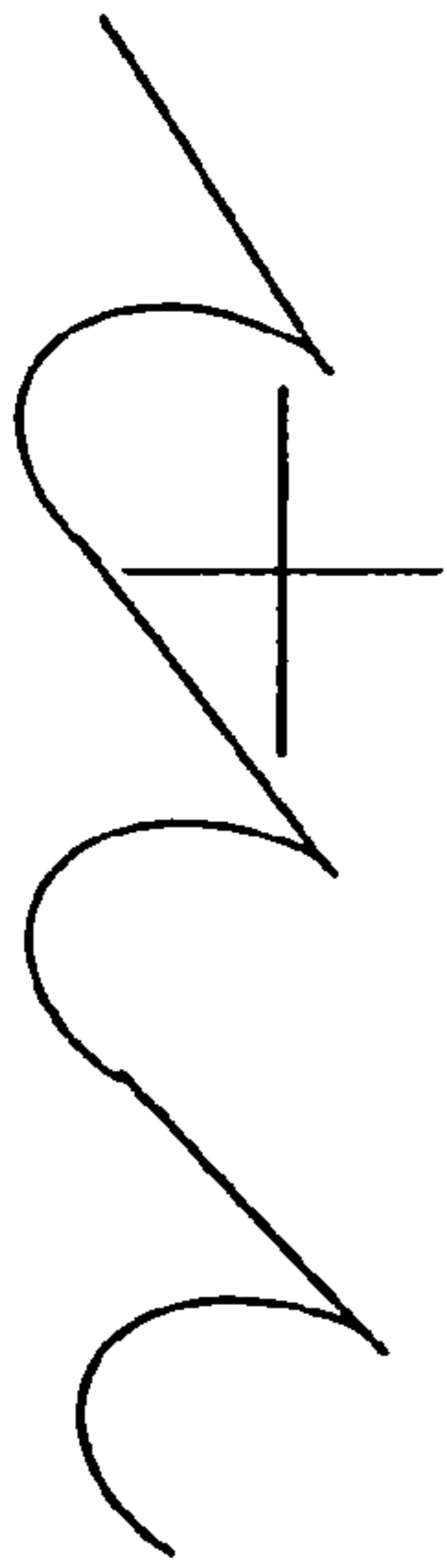


Figure 6A

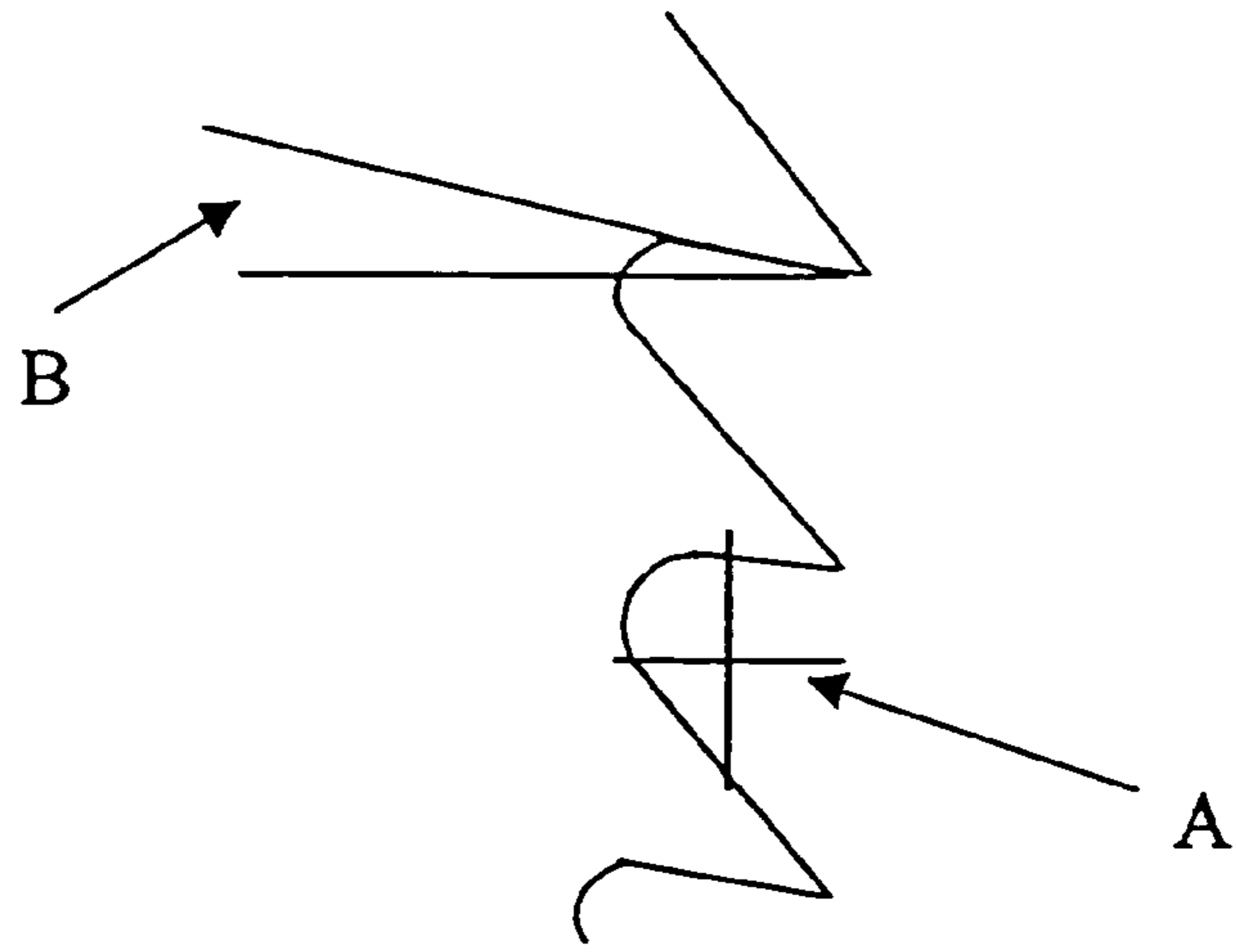


Figure 6B

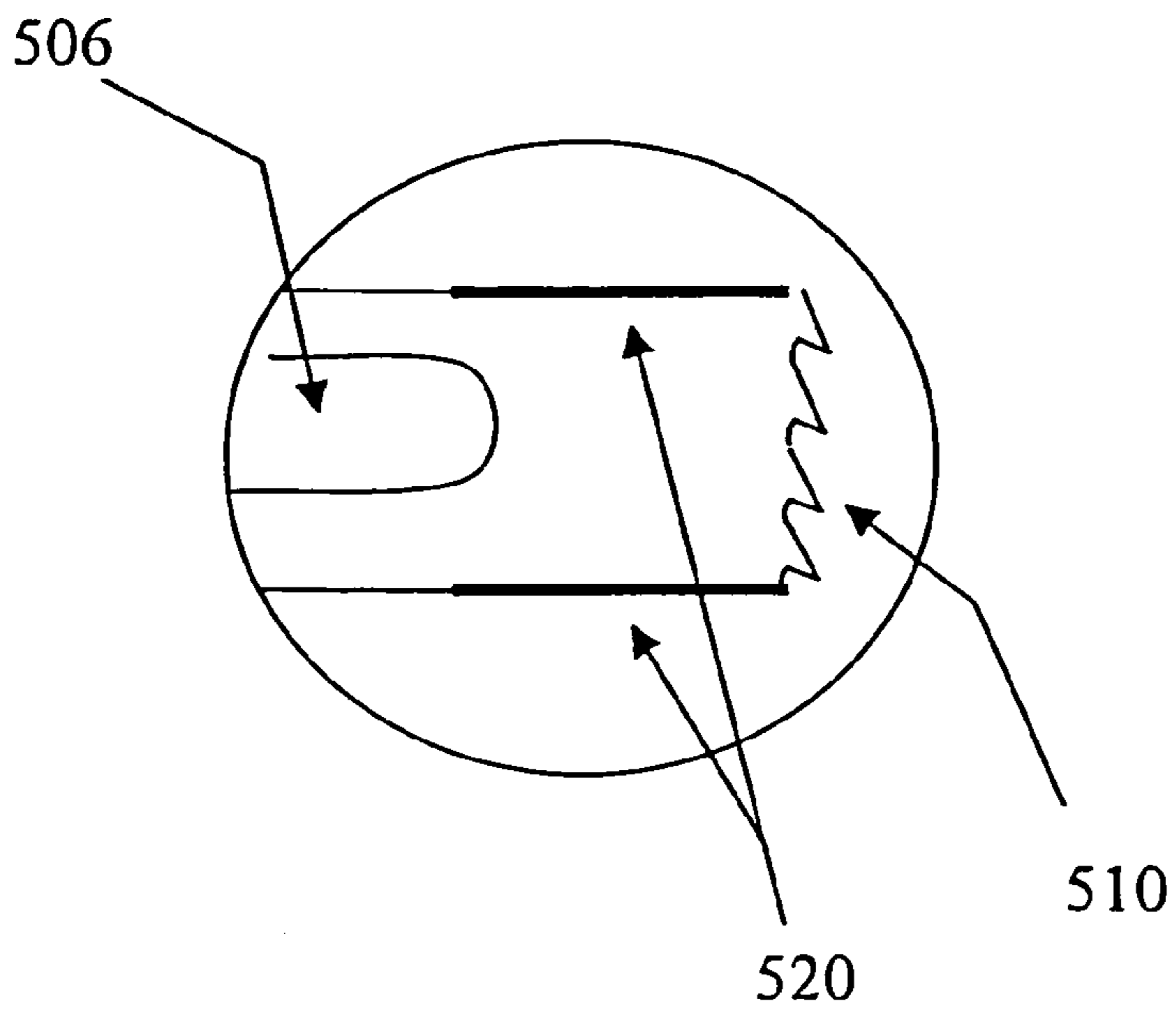


Figure 7

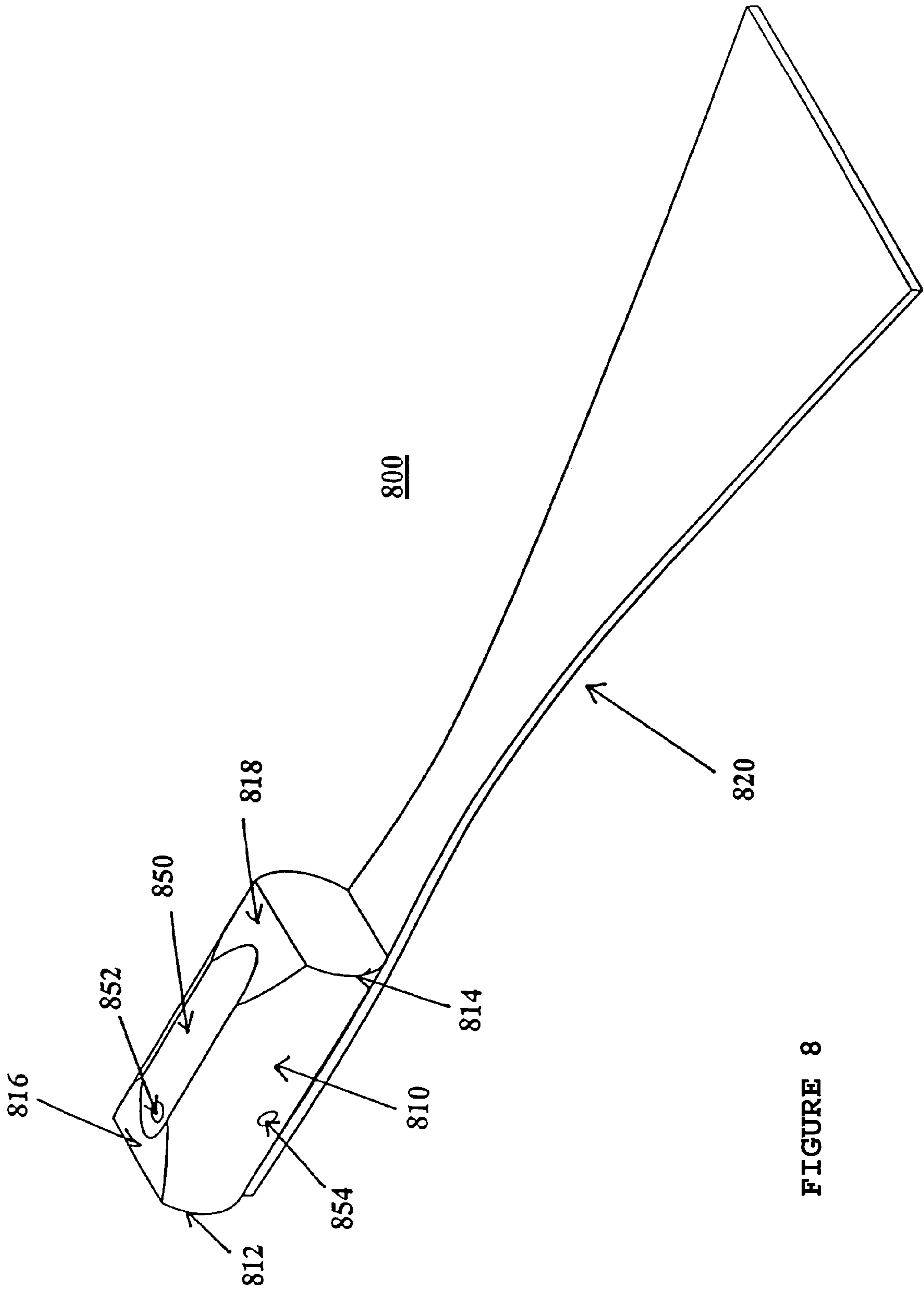


FIGURE 8

1

## MATERIALS AND METHODS FOR IMPROVED BONE TENDON BONE TRANSPLANTATION

This application is a continuation of U.S. Ser. No. 09/528, 034, filed Mar. 17, 2000, now allowed, which is a continuation-in-part of U.S. Ser. No. 09/481,319, filed Jan. 11, 2000, now U.S. Pat. No. 6,497,726.

### BACKGROUND OF THE INVENTION

Orthopedic medicine is increasingly becoming aware of the vast potential and advantages of using bone/tendon/bone grafts to repair common joint injuries, such as Anterior Cruciate Ligament (ACL) or Posterior Cruciate Ligament (PCL) tears. One technique that is currently used for repairing these types of injuries involves surgically reconnecting the torn portions of a damaged ligament. However, this technique is often not possible, especially when the damage to the ligament is extensive. To address situations where the damage to the joint ligaments is severe, another technique commonly performed involves redirecting tendons to provide increased support to a damaged knee. These conventional techniques are not without their shortcomings; in most cases, the repaired joint lacks flexibility and stability.

The recent utilization of bone/tendon grafts has dramatically improved the results of joint repair in cases of severe trauma. Even in cases of extensive damage to the joint ligaments, orthopedic surgeons have been able to achieve 100 percent range of motion and stability using donor bone/tendon grafts.

Despite these realized advantages, there have been some difficulties encountered with utilizing bone/tendon grafts. For example, surgical procedures involving transplantation and fixation of these grafts can be tedious and lengthy. Currently, bone/tendon/bone grafts must be specifically shaped for the recipient during surgery, which can require thirty minutes to over an hour of time. Further, surgeons must establish a means of attaching the graft, which also takes up valuable surgery time.

Another difficulty associated with using bone/tendon grafts is that there is a limited supply. This can result in a patient having to choose an inferior procedure simply based on the lack of availability of tissue. Accordingly, there is a need in the art for a system that addresses this and the foregoing concerns.

### SUMMARY OF THE INVENTION

The subject invention concerns a novel bone tendon bone graft (BTB) that facilitates an easier and more efficient surgery for reconstructing ligaments in a joint. One aspect of the subject invention pertains to a BTB that comprises a tendon and two bone blocks positioned at opposite ends of the tendon, wherein the bone blocks are pre-shaped for uniform and consistent alignment into a recipient bone.

In a specific aspect, the subject invention pertains to a bone tendon bone graft useful in orthopedic surgery comprising one or more bone blocks, and a tendon attached to said one or more bone blocks; wherein said one or more bone blocks is cut to provide a groove sufficient to accommodate a fixation screw. Alternatively, the subject invention pertains to a bone tendon bone graft useful in orthopedic surgery comprising one or more bone blocks and a tendon attached to said one or more bone blocks, wherein said one or more bone blocks is pre-shaped into a dowel.

2

A further aspect of the subject invention pertains to a method of obtaining a plurality of bone tendon bone grafts comprising excising a first bone plug having attached thereto a tendon or ligament; and excising a second bone plug having attached thereto a tendon or ligament; wherein said first bone plug and said second bone plug are derived from contiguous bone stock and overlap such that excision of said first bone plug or said second bone plug forms a groove in the bone plug that is excised subsequent to the other.

In yet another aspect, the subject invention pertains to a method of conducting orthopedic surgery on a human or an animal comprising obtaining a bone tendon bone graft, said graft comprising a tendon or ligament having two ends, and one or more bone blocks attached to said tendon or ligament, wherein at least one of said one or more bone blocks has a groove suitable for accommodating a fixation screw.

An alternative aspect of the invention pertains to an implant comprising a bone block and a tendon, wherein the bone block comprises a groove for accommodating a fixation screw.

Yet a further aspect of the subject invention pertains to a BTB core cutter for harvesting BTB grafts in accordance with the principles of the subject invention.

These and other advantageous aspects of the subject invention are described in further detail below.

### DETAILED DESCRIPTION OF THE DRAWINGS

FIG. 1 shows an embodiment of a BTB having a groove with a thread profile disposed thereon.

FIG. 2 shows a side view of three different embodiments of BTBs in accordance with the subject invention.

FIG. 3 depicts a frontal view of a donor area for harvesting BTBs in accordance with the teachings herein.

FIG. 4 is a depiction of another embodiment of the invention illustrating a reconstruction of an injured area through implantation of a BTB in accordance with the teachings herein.

FIG. 5 shows a side view of a BTB core cutter of the subject invention designed for harvesting BTB grafts.

FIG. 6A shows a close up view of a teeth configuration that is less desired for use with the subject invention.

FIG. 6B shows a close up view of a preferred embodiment of the teeth of the embodiment shown in FIG. 5.

FIG. 7 is a blown up view of the circled region as shown in FIG. 5.

FIG. 8 is three dimensional side view of a further embodiment of the subject BTB that comprises one block that is tapered on both ends.

### DETAILED DISCLOSURE OF THE INVENTION

Referring to FIG. 1, there is shown an embodiment directed to a BTB **100** comprising a first bone block **110** and a second bone block **120** interconnected by a tendon **130**, wherein each bone block has been pre-shaped into dowels. The term "tendon" as used herein is intended in its broad sense and refers to fibrous connective tissue for use in grafts, such as, but not limited to, tendons, ligaments and demineralized bone. The terms "BTB" or "bone tendon bone graft" as used herein refer to a graft implant that comprises one or more tendon portions and one or more bone portions. The BTB is preferably isolated from the knee of a donor. However, in view of the teachings herein, those skilled in the art will readily appreciate that other areas of the body are suitable, albeit less preferred, for harvesting BTBs according to the subject invention, such as, but not limited to, the Achilles tendon/calcaneus



region or shoulder region. In addition to BTBs having a tendon portion derived from naturally occurring tendon or ligament harvested from a donor, other examples of suitable implants would be readily appreciated by those skilled in the art, such as, but not limited to, segmentally demineralized bone (International Pub. No. WO/99/21515). In a more preferred embodiment, one of the bone blocks is derived from the patella while the other is derived from the end of the tibia, and the tendon is derived from the patellar tendon.

To facilitate placement of a fixation screw, the dowels are preferably machined down the length of the bone block to form radius cuts **115**, **125**. The radius cuts **115**, **125** aid in the attachment of the graft to recipient bone because they provide a groove to position a fixation screw, which results in increased surface area at the contact between the bone block and the screw. The radius cuts **115**, **125** provide the additional advantage of increasing the pull out loads of the bone block, as well as filling of "dead" space in the tunnel.

Fixation methods known in the art can be used in accord with the principles of the subject invention, which include, but are not limited to, staples, buttons, screw and washer, interference screws, and self-taping screws. In a preferred embodiment, fixation is accomplished by interference screws and/or self-taping screws. In an even more preferred embodiment, the radius cuts **115**, **125** contain a thread profile **135** that matches the thread profile of the fixation screw, thereby further increasing the stability of fixation.

Referring now to FIG. 2, three different embodiments of the subject BTBs are shown. FIG. 2A shows an embodiment that comprises a basic configuration of the subject BTBs. Bone blocks **210** and **220** are in a pre-shaped dowel form with no groove thereon, and are connected by tendon **100**. FIG. 2B shows another version of the BTB, wherein the bone blocks are preshaped into dowels with tapered ends. Bone block **212** is a dowel that has a proximal tapered region **216** in relation to tendon **200**, and bone block **214** is preshaped into a dowel that has a distal tapered region **218** in relation to tendon **200**. FIG. 2C illustrates a preferred version of the invention, which has a bone block **230** with a proximal tapered region **239** and a groove **238** positioned on the bone block **230**. This version also comprises a second bone block **234** with a distal tapered region and a groove **236** positioned on bone block **234** as well. The embodiments shown in FIGS. 2B-C are tapered such that implantation into a pre-formed tunnel in recipient bone is preferred to occur in the direction of the arrow (see also FIG. 4).

Referring to FIG. 3, an illustration of a donor area **300** is depicted, wherein three separate grafts **335**, **345**, and **355** are harvested. As shown, the three different grafts individually have at least one bone block **330**, **340**, and **350**. While the sequence of harvesting the grafts is not critical, preferably, graft **335** is excised first, followed by excision of the outside grafts **345**, **355**. Excising graft **335** first results in the automatic cut in the other donor areas, thereby producing a groove in the bone blocks **340**, **350** of the other grafts upon excision. In a preferred embodiment, the donor area is located at the top of the Tibia at the insertion of the patellar tendon **320**. In an even more preferred embodiment, the donor area extends the length of the patellar tendon to the patella, wherein bone blocks are excised from the patella.

The bone blocks can be extracted with the use of conventional tools and protocols routinely practiced in the art, such as core cutter and hole saws. In a preferred embodiment, the bone blocks can be extracted through the use of a BTB bone cutter according to the teachings further described below.

The extracted bone blocks **330**, **340**, and **350** are generally shaped like a plug or dowel and are preferably further shaped

by machining through conventional methods known in the art. In a specific embodiment the dowel is machined into dimensions suitable for various surgical procedures. The machining is preferably conducted on a graduated die, a grinding wheel, a lathe, or machining tools may be specifically designed and adapted for this purpose in view of the teachings herein. Preferred dimensions for the dowels include 8 mm, 9 mm, 10 mm, 11 mm, and 12 mm in diameter. Reproducibility of the product dimensions is an important feature for the successful use of such grafts in the clinical setting.

In a specific embodiment, the subject invention is directed to a method of repairing an injured cruciate ligament in the knee involving the implantation of a BTB. FIG. 4 illustrates this procedure, and shows a femur **400** and tibia **410** having tunnels formed therein, **466** and **462**, respectively, for receiving BTB **430**, which comprises two bone blocks **432** and **434** connected by tendon **433**. To aid in guiding the BTB **430** through tunnel **462**, sutures **460** are optionally engaged to bone block **432**, which allow a surgeon to pull the BTB **430** through tunnel **462** where the sutures **460** can then be removed. Once the BTB **430** is properly situated in tunnels **462** and **466**, the BTB **430** is secured in the recipient bone by interference screws **440**. The interference screws **440** are preferably self taping and are engaged by rotation in the space between grooves **438** and **436** and the inner walls of tunnels **466** and **462**, respectively. In an even more preferred embodiment, the BTB can be pre-marked with alignment markings. Such markings can be positioned on the BTB to aid the surgeon in visualizing the depth of the BTB in the tunnels formed for receiving the BTB, as well as visualizing bone ligament junctions and rotation of the BTB.

Referring now to FIGS. 5-7, another embodiment of the subject invention is shown that is directed to a BTB harvesting device, such as core cutter **500** that comprises a shaft **502** having a first end **503** and a second end **505**. The first end **503** of the shaft **502** preferably has a cavity **501** longitudinally disposed thereon, which is designed for engaging a drill, such as by insertion of a Jacob's chuck attached to a power drill (e.g., Dupuy). The second end **505** of the shaft **502** can be attached to a first end **512** of a hollow cylinder **504**. The second end **514** of the cylinder **504** preferably has teeth **510** disposed thereon. In a preferred embodiment the cylinder has at least one slot **506** disposed on its surface to aid in the removal of the cut graft tissue from the core cutter **500**. The slot **506** also provides a means to wash the graft during the extraction procedure to thereby decrease the chance of frictional burning of the graft. In a preferred embodiment, the shaft **502** is approximately 90 mm in length, the cylinder **504** is approximately 50 mm in length, and the slot **506** is approximately 30 mm in length. In an even more preferred embodiment, the first end of the hollow cylinder **512** has a chamfered portion **522** which angles down to the shaft **502**.

A blown up view of the core cutter teeth **510** is illustrated in FIG. 6. It is preferred that the radius of the teeth A and rake angle of the teeth B (also referred to as a bottom angle) are of appropriate values as to avoid failure (e.g. bending or breaking) of the teeth, as well as undesired damage to the graft. For example, FIG. 6A shows an unacceptable tooth pattern wherein the radius A and bottom angle B are too large, resulting in insufficient support structure for the tooth and inevitable failure. According to the subject invention, a core cutter having a diameter of approximately 10-11 mm preferably has approximately 14 teeth, with a tooth radius A of approximately 20-30 mm (25 mm being more preferred) and a bottom angle B of approximately 10-20 degrees (15 degrees being more preferred). For core cutters designed for smaller or



larger bone blocks, the foregoing dimensions are preferably maintained, while the number of teeth are appropriately decreased or increased. In a preferred embodiment, the number of teeth are decreased or increased by two for every millimeter below or above, respectively, the 10-11 mm cylinder diameter. For example, a core cutter having a 12 mm cylinder diameter would preferably have about 16 teeth.

A blown up view of an end section (circle shown in FIG. 5) of the cylinder 504, is shown in FIG. 7, which illustrates a preferred embodiment of the cylinder 504 wherein the internal diameter (ID) is decreased slightly by adding a relief thickness 520 to the inner surface of the cylinder 504. This embodiment provides an additional convenience when using a size gauging device (e.g. ring) for selecting extracted bone blocks that are within desired parameters. For example, the selection of a BTB through a 10 mm sized gauging device would preferably require the BTB to be a slight fraction smaller in diameter than the gauging device, otherwise any insignificant irregularity in the shape of the BTB might cause it to fail to pass through the gauging device. The relief thickness 520 decreases the ID of the cylinder 504, thereby effectuating this slight modification to the BTB.

Shown in FIG. 8 is a further embodiment 800 of the subject BTB that is especially adapted for implantation during knee surgery, wherein the implantation and securement of the BTB is bi-directional. BTB embodiment 800 comprises one bone block portion 810 and one tendon portion 820. A preferred area from which embodiment 800 is harvested would be the heel, thigh, or shoulder. More preferably, the area from which embodiment 800 is harvested is the heel or thigh, whereby tendon portion 820 is derived from an Achilles tendon or quadriceps tendon of a donor. The bone block portion 810 comprises two ends 812 and 814 which both comprise a tapered region 816 and 818, respectively. The presence of the two tapered regions 812 and 814 allows for the BTB embodiment 800 to be inserted and secured bi-directionally, which means, for example, implantation in either the tibial 462 or femoral 466 tunnels as discussed above in reference to the method diagrammed in FIG. 4. Of course, the site of implantation could be approached from a superior point of entry, i.e., establishing a through-tunnel in the femur as opposed to the tibia; BTB embodiment 800 would be suitable for securement in either tunnels in such alternative procedure as well. Further, the bone block 810 can be provided with a groove 850 to aid in the securement of the implant. In addition, during implantation, it may be desirable to have a means for manipulating the implant, such as by sutures or graft insertion tools. Accordingly, BTB embodiment 800 is provided with preformed graft manipulation holes 852 and 854 for receiving a suture and/or graft insertion tools. By way of example of illustrating the orientation of the graft manipulation holes, holes 852 and 854 are shown as being vertical or horizontal, respectively, to the axis of the bone block 810. The preformed graft manipulation holes can be made by conventional methods, such as by drilling. Appropriate tools for insertion into preformed holes 852 and 854 will easily be appreciated by those skilled in the art. Preferably, the graft insertion tool(s) used comprise an end having a shape and size suitable for insertion into the graft manipulation holes.

Those skilled in the art will appreciate that the graft may be an autograft, allograft, or xenograft. Xenograft implants may further require treatments to minimize the level of antigenic agents and/or potentially pathogenic agents present in the graft. Techniques now known, or those which are later developed, for preparing tissue such that it is suitable for and not rejected by the recipient are incorporated herein. In cases where the graft is an allograft or xenograft, a donor is prefer-

ably screened for a wide variety of communicable diseases and pathogens, including human immunodeficiency virus, cytomegalovirus hepatitis B, hepatitis C and several other pathogens. These tests may be conducted by any of a number of means conventional in the art, including, but not limited to, ELISA assays, PCR assays, or hemagglutination. Such testing follows the requirements of the following associations: (a) American Association of Tissue Banks. Technical Manual for Tissue Banking, Technical Manual-Musculoskeletal Tissues, pages M19-M20; (b) The Food and Drug Administration, Interim Rule, Federal Register, Vol. 58, No. 238, Tuesday, December 14, Rules and Regulations, 65517, D. Infectious Disease Testing and Donor Screening; (c) MMWR, Vol. 43, No. RR-8, Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs, pages 4-7; (d) Florida Administrative Weekly, Vol. 10, No. 34, Aug. 21, 1992, 59A-1.001-014, 59A-1.005(12)(c), F.A.C., (12)(a)-(h), 59A-1.005(15), F.A.C., (4) (a)-(8). In addition to a battery of standard biochemical assays, the donor, or their next of kin can be interviewed to ascertain whether the donor engaged in any of a number of high risk behaviors such as having multiple sexual partners, suffering from hemophilia, engaging in intravenous drug use etc. Once a donor has been ascertained to be acceptable, the tissue for obtention of the BTBs as described above are recovered and cleaned.

The teachings of all patents and publications cited throughout this specification are incorporated by reference in their entirety to the extent not inconsistent with the teachings herein.

It should be understood that the examples and embodiments described herein are for illustrative purposes only and that various modifications or changes in light thereof will be suggested to persons skilled in the art and are to be included within the spirit and purview of this application and the scope of the appended claims.

#### Example 1

##### Procedure for Harvesting of Crude BTB for Patellar Tendon Tibial Donor

A BTB was harvested according to the following procedure:

1. Using blunt and sharp dissection remove the three layers of connective tissue from the anterior portion of the tendon.
2. Using scalpel or scissors cut along the medial and lateral borders of the tendon. Use the scissors to bluntly dissect under the tendon to separate it from the fat layer.
3. Cut around the Patellar block to separate it from the proximal tibia and distal femur. Leave approximately 4 cm of quadriceps tendon attached to the patellar if required. If no quadriceps tendon attachment is specified then remove quadriceps from patellar completely using sharp dissection.
4. Pull tendon away from capsule and remove all excess adipose tissue to the point of tibial insertion.
5. With a saw make a transverse cut through approximately the tibial tuberosity about 30 mm from the tendon insertion point. Make a similar cut about 5 mm proximal to the insertion point, which will remove the tibial plateau.
6. With a saw, cut and square the sides of the tibia bone block even with the tendon.
7. With a saw cut and square the patella block on three sides (if quadriceps tendon is still attached square off only the medial and lateral sides).
8. Remove all extraneous soft tissue and cartilage from the patella, tibial tuberosity and tendon.



7

9. To hemisect the patellar tendon use a scalpel to divide the tendon into a medial half and a lateral half. Each half should be 14 mm or greater unless otherwise specified.

10. Using a saw, split the patella block and the tibia block in half following the same medial/lateral line used to split the tendon.

11. Thoroughly lavage the bone blocks with sterile water or saline.

#### Example 2

##### Procedure for Forming Patellar Tendons with Preshaped Dowels for Patellar Tendon Tibial Donor

A BTB was harvested according to the following procedure:

1. Using blunt and sharp dissection remove the three layers of connective tissue from the anterior portion of the tendon.

2. Using a scalpel or scissors cut along the medial and lateral borders of the tendon to separate it from the fat layer.

3. Cut around the Patellar block to separate it from the proximal tibia and distal femur.

4. Pull tendon away from capsule and remove all excess adipose tissue to the point of tibial insertion.

5. With a saw make a transverse cut through the tibial tuberosity about 30 mm from the tendon insertion point. Make a similar cut just proximal to the insertion point removing the tibial plateau. Make another cut across the coronal plane 20-30 mm posterior from the insertion point.

6. With a saw square the sides of the tibia bone block.

7. With a saw cut and square the patella block on the three sides.

8. Attach a vice to the tabletop. Place the tibia bone block in the vice so that it holds it along the proximal and distal sides. The distal side of the bone block should be facing the processor with the tendon going away from them. Tighten the vice so that it holds the bone securely but does not crush it.

9. Attach a Jacob's chuck to a drill and insert the appropriate size cutter. Tighten the chuck with the chuck key. Note: At least two plugs should be cut from each bone block.

10. Position the cutter against the bone block so the teeth of the cutter will skim just over the top of the tendon without catching the tendon. Position the cutter so that the maximum attachment is obtained throughout the length of the bone plug.

11. Turn drill on and begin drilling the plug. When the cutter nears the end of the plug, slow the drill until the cutter just breaks through the proximal end of the bone block. Remove the plug from the cutter and drill without damaging the tendon.

12. Repeat steps 10 and 11 for the second plug.

13. Using scissors or a scalpel hemisect the tendon into medial and lateral halves.

14. Remove the excess bone from the table vice and place the patella bone block into the vice so that it holds it along the medial and lateral sides of the block. The proximal side of the patella should be facing the processor with the tendon going away from them. Tighten the vice so that it holds the bone block securely but does not crush it.

15. Repeat steps 10 and 11 for both plugs.

16. When the plugs are completed, remove the excess patella bone from the vice and detach the vice from the table.

17. Remove the cutter from the Jacob's chuck and place a 1.5 mm drill bit into the chuck. Tighten with the chuck key.

18. Using a saw, cut each plug to approximately 30 mm in length (no less than 25 mm)

19. Using the Arthrex clamp, place the plug into it with the end of the plug flush with the end of the clamp. Position the

8

plug in the anterior/posterior position. Using the first guide hole nearest the flush end of the plug, drill a hole through the plug with the 1.5 mm drill bit. Turn the plug 180 degrees so that it is positioned in the medial/lateral position. Use the second guide hole from the flush end of the plug to drill a second hole through the plug.

20. Repeat step 19 for all bone plugs.

21. Using a sizing apparatus insert each bone plug into the appropriate size gauge. The entire BTB should slide completely through easily. Trim if necessary.

22. Thoroughly lavage bone plugs with sterile water or saline.

What is claimed is:

1. A recovered, cleaned and pre-shaped human allograft implant useful for implantation by fixation in a bone tunnel during orthopedic surgery, comprising a first human bone block in a pre-shaped cylindrical dowel form and further comprising a natural insertion of a first human tendon into said first human bone block, wherein said natural insertion occurs between one of the following bone-tendon pairs,

- a. patellar bone and patellar tendon,
- b. patellar bone and quadriceps tendon,
- c. tibial bone and patellar tendon, or
- d. calcaneus bone and Achilles tendon; and

wherein said tendon runs along at least a portion of the length of said cylindrical dowel and said tendon forms at least a portion of an outer circumferential surface of said cylindrical dowel; wherein the portion of the outer circumferential surface maintains essentially the same contour as the rest of the cylindrical dowel.

2. The pre-shaped human allograft implant of claim 1, wherein said first human bone block comprises a human calcaneal bone block in a pre-shaped cylindrical dowel form with no groove thereon and wherein said natural insertion comprises a natural insertion of the human Achilles tendon into said human calcaneal bone block, and wherein said first human tendon comprises a human Achilles tendon portion derived from a naturally occurring human Achilles tendon.

3. The pre-shaped human allograft implant of claim 1, wherein said first human bone block comprises a human tibial bone block in a pre-shaped cylindrical dowel form with no groove thereon and wherein said natural insertion comprises a natural insertion of the human patellar tendon into said human tibial bone block, and wherein said first human tendon comprises a human patellar tendon portion derived from a naturally occurring human patellar tendon, said human patellar tendon portion further naturally attached to a human patellar bone block.

4. The pre-shaped human allograft implant of claim 1, wherein said patellar tendon, or said quadriceps tendon or said Achilles tendon is hemisected.

5. The pre-shaped human allograft implant of claim 4, wherein said bone block has at least one side which is cut even with the tendon.

6. The pre-shaped human allograft implant of claim 1, wherein said first human bone block is in a pre-shaped cylindrical dowel form with no groove thereon.

7. The pre-shaped human allograft implant of claim 1, wherein said first human bone block is tapered.

8. The pre-shaped human allograft implant of claim 1, wherein said first human bone block is not tapered.

9. A pre-shaped human allograft implant, useful in orthopedic surgery on a human, and isolated from a donor area in the knee of a human donor, said donor area located at the top of a tibia at an insertion of a patellar tendon extending the length of the patellar tendon to the patella, said implant comprising:



9

- a. a human tibial bone block in a pre-shaped cylindrical dowel form and further comprising a natural insertion of the human patellar tendon into said human tibial bone block,
- b. a human tendon portion derived from naturally occurring human patellar tendon, said human patellar tendon further naturally attached to, and
- c. a human patellar bone block in a pre-shaped cylindrical dowel form; and

wherein said tendon portion runs along at least a portion of the length of at least one of said cylindrical dowels and said tendon portion forms at least a portion of an outer circumferential surface of at least one of said cylindrical dowels; wherein the portion of the outer circumferential surface maintains essentially the same contour as the rest of said cylindrical dowels.

**10.** The pre-shaped human allograft implant of claim **9**, wherein said human tibial bone block is in a pre-shaped cylindrical dowel form with no groove thereon.

**11.** The pre-shaped human allograft implant of claim **10**, wherein said human patellar bone block is in a pre-shaped cylindrical dowel form with no groove thereon.

**12.** A human allograft implant portion isolated from a donor area in the knee of a human donor, useful in preparation of an implant for orthopedic surgery, comprising:

- a. a human tibial bone block derived from a tibia of said human donor and further comprising a natural insertion of a patellar tendon into said tibia,
- b. a human patellar tendon divided into two tendon portions following a medial/lateral line, said patellar tendon further naturally attached to, and
- c. a human patellar bone block,

wherein at least one of said human patellar bone block or said human tibial bone block is divided following said medial/lateral line dividing said human patellar tendon; and

wherein said tendon runs along at least a portion of the length of either said human tibial bone block or human patellar bone block or both, and said tendon forms at least a portion of an outer circumferential surface of either said human tibial bone

10

block or human patellar bone block or both; wherein the portion of the outer circumferential surface maintains essentially the same contour as the rest of either said human tibial bone block or human patellar bone block or both.

**13.** The human allograft implant portion of claim **12**, wherein said human patellar tendon is split in half.

**14.** The human allograft implant portion of claim **12**, wherein at least one of said tendon portions of said human patellar tendon is 14 mm or greater in width.

**15.** The human allograft implant portion of claim **12**, wherein said human patellar bone block is cut and squared on at least three sides.

**16.** The human allograft implant portion of claim **12**, wherein said human tibial bone block further comprises,

- a. at least a portion of a tibial tuberosity,
- b. a natural insertion of a patellar tendon into said tibia, and
- c. a first transverse cut bone block end approximately through said tibial tuberosity of said human tibia.

**17.** The human allograft implant portion of claim **16**, further comprising a second transverse cut bone block end just proximal to the tendon insertion point of said human patellar tendon.

**18.** A crude shaped construct useful in orthopedic surgery on a human, comprising:

- a. an allograft Achilles tendon naturally attached to a section of calcaneal bone, and
- b. a natural insertion site of said Achilles tendon,
- c. a portion of calcaneal bone distal to said natural insertion site, and
- d. a medial/lateral division of said tendon,

wherein at least one side of said portion of calcaneal bone is cut even with said division of said tendon; and wherein said tendon runs along at least a portion of the length of said portion of calcaneal bone and said tendon forms at least a portion of an outer circumferential surface of said portion of calcaneal bone wherein the portion of the outer circumferential surface maintains essentially the same contour as the rest of the portion of the calcaneal bone.

\* \* \* \* \*